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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/565,763	06/05/2006	Vincenzo De Leo	SER.105	2323

23557 7590 10/01/2010

SALIWANCHIK LLOYD & SALIWANCHIK
A PROFESSIONAL ASSOCIATION
PO Box 142950
GAINESVILLE, FL 32614

EXAMINER	
BORGHEST, CHRISTINA M	

ART UNIT	PAPER NUMBER
1649	

NOTIFICATION DATE	DELIVERY MODE
10/01/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

euspto@slspatents.com

Advisory Action Before the Filing of an Appeal Brief	Application No.	Applicant(s)	
	10/565,763	DE LEO ET AL.	
	Examiner	**Art Unit**	
	Christina Borgeest	1649	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 27 August 2010 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

   a) ☒ The period for reply expires *3* months from the mailing date of the final rejection.

   b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

   Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☐ They raise the issue of new matter (see NOTE below);
   (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).

5. ☒ Applicant's reply has overcome the following rejection(s): See Continuation Sheet.

6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
   The status of the claim(s) is (or will be) as follows:
   Claim(s) allowed: _____.
   Claim(s) objected to: _____.
   Claim(s) rejected: *12,16-28 and 31-43*.
   Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).

9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).

10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.

12. ☐ Note the attached Information *Disclosure Statement*(s). (PTO/SB/08) Paper No(s). _____

13. ☐ Other: _____.

/Bridget E Bunner/
Primary Examiner, Art Unit 1647

Continuation of 5. Applicant's reply has overcome the following rejection(s): Rejection under 35 U.S.C. 112, first paragraph (Scope of Enablement) of claims 12, 16-28 and 31-43.

Continuation of 11. does NOT place the application in condition for allowance because: The amendment does not overcome the rejection of claims 12, 16, 17, 19-27, 31-33, 35-39 and 41-43 under 35 U.S.C. 102(b) as being anticipated by Acosta et al. as evidenced by Moeman et al. Further, the amendment does not overcome the rejection of claims 18 and 34 udner 35 U.S.C. 103(a) as being unpatentable over Acosta et al. as applied to claims 12, 16, 17, 19-27, 31-33, 35-39 and 41-43 above, and further in view of Loumaye et al. Finally, the amendment does not overcome the rejetion of claims 28 and 40 udner 35 U.S.C. 103(a) as being unpatentable over Acosta et al. as applied to claims 12, 16, 17, 19-27, 31-33, 35-39 and 41-43 above, and further in view of Bouloux et al. Note, that all cited references are already of record.

(i) Applicant argues at p. 6 that the claims require diagnosing a male as having XX disomy or YY disomy and administration of FSH for reducing or treating the rate of gamete numerical chormosomal alterations in a male, and Acosta et al. do not teach diagnosis.

(ii) Applicant argues at p. 7, that aneuploidy, diploidy or disomy is determined by FISH and that Moeman et al. indicate that "although analysis of semen parameters could provide some indication of the function of the testis and spermatozoa, it does not provide information on the condition of the male genome contained in sperm heads" and that the sperm parameters taught in Acosta et al. cannot meet the step of diagnosing XX or YY disomy.

This argument has been fully considered but is not found persuasive. Moeman et al. goes on to say at the next paragraph at p. 382, that the objective of their study was "to determine the incidence of sperm disomy in cases of male infertility with idiopathic severe oligoasthenoteratozoospermia or OAT." In other words, Moeman and colleagues were trying to determine whether men diagosed with OAT using the traditional sperm parameters for diagnosis (i.e. as taught in Acosta), also have a higher rate of disomy. Thus, the quote cited by Applicant is taken out of context, because what Moeman and colleagues actually found was that patients diagnosed with OAT using traditional sperm parameters also suffered from an increased incidence of disomy (see p. last line in 383 through 1st line of p. 384: "Significantly higher frequencey was found in spermatozoa from OAT cases for XX disomy and XY disomy than controls..." This means that the severe OAT cases that were diagnosed with traditional sperm parameters also had significant XX and XY disomy, and that the severely oligoasthenteratozoospermic men in Acosta et al. represent the same patient population being treated with the same agent (FSH) as the instant claims. See MPEP 2112 [R-3]:

I. SOMETHING WHICH IS OLD DOES NOT BECOME PATENTABLE UPON THE DISCOVERY OF A NEW PROPERTY
"[T]he discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer." Atlas Powder Co. v. Ireco Inc., 190 F.3d 1342, 1347, 51 USPQ2d 1943, 1947 (Fed. Cir. 1999). Thus the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. In re Best, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977).

The issue is that the later discovery of the previosuly unappreciated property that severe OAT is associated with disomy does not change the fact that the prior art was already teaching diagnosis of men with severe OAT and their treatment with FSH. What Moeman et al. demonstrate is that a diagnosis of severe OAT using traditional sperm parameters (as in Acosta et al.) also isolates a population of men with sperm disomy.

Applicant's arguments with regard to the rejection under 103(a) are a restatement of the argument that Acosta et al. fail to teach a step of diagnosing XX or YY disomy, thus the Examiner's reply to arguments under 102(b) are hereby incorporated in response.